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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,795	12/06/2001	John P. Morseman	031676.0263	8799

21967 7590 01/14/2004

HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/14/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,795

Applicant(s)

MORSEMAN ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 10-12 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 7 is/are allowed.
- 6) ☒ Claim(s) 2 is/are rejected.
- 7) ☒ Claim(s) 3,4 and 9 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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1) Newly submitted claims 8 and 10-12 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

a) The method of preparation of claim 8 does not prepare either the contents of the "single vessel" of original claim 1 (containing NHS, carbodiimides and a label) nor the contents of the "single vessel" of original claim 7 (containing a label derivatized with a heterofunctional reagent and a means for activating the reagent). Further, the method of preparation of claim 8 requires the "sequestration" of reagents and "step for releasing sequestration" not addressed in either of claims 1 and 7. The limitation "sequestration" (claim 8) does not necessarily imply a "dry form" of the reagents (claims 1 and 7). Claim 8 is distinct from the originally examined claims for the reason that different patentability considerations would be involved in addressing a method of preparation which does prepare the products already examined.

b) The "single vessel" of newly presented claim 10 contains a different set of components than those present in the "single vessels" of original claims 1 and 7. The "label" of claim 10 is not required to contain either an amine or a carboxyl group as required by claim 1 nor is it required that the "label" of claim 10 be "derivatized with one functionality of a heterofunctional reagent" as in claim 7 (claim 10 requires the presence of "a label" and a "bifunctional reagent" separately). Claims 10-12 are distinct from the originally examined claims for the reason that different patentability considerations would be involved in addressing products comprising different sets of components.

c) The steps recited in claim 9 do not correlate with the steps recited in claim 8. For example, step b. of claim 9 does not further define any one of steps i. – iii. of claim 8. However, since claim 9 is apparently meant to be equivalent to original claim 6 (Remarks of October 28, 2003, page 4, **A.**), claim 9 is examined on the merits to the extent that it contains the same subject matter as original claim 6. Claim 9 should be amended to be in independent form.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 8 and 10-12 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-4, 7 and 9 (to the extent that it is of the same scope as original claim 6) are examined on the merits in this Office action.

2) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 2 is again rejected under 35 USC 112, second paragraph, as being indefinite, incomplete and confusing. The preamble of the claim recites "a method for conjugating label to target moiety". However, there is no step recited which requires the addition/presence of any "target moiety". The term "wherein a target moiety is conjugated to the label" does not specify in which step the "target" is added (see paragraph **7)a)** of the July 30, 2003 Office action).

Applicant's arguments filed October 28, 2003 have been fully considered but they are not persuasive. Applicant argues that "one skilled in the art would be above to understand that hydrating the dry powder in the buffer solution containing the target protein is actually the step of adding the target moiety for conjugation". However, the "components in dry form" ("dry powder"?) of claim 2 consist only of "a label", "NHS", and "a carbodiimides"; no "target moiety" is required or "added".

4) Claims 1 and 7 are allowed.

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5) Claims 3 and 4 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6) Claim 9 is objected to as being dependent upon a non-elected base claim. If presented as an independent claim, claim 9 would be allowable.

7) THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.

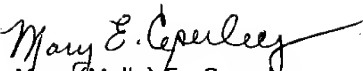
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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January 12, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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